Special 510(k): Device Modification
SIEMENS INFINITY Explorer

510(k) SUMMARY
as required per 807.92(c)

MAR 21 2003

Submitters Name, Address:
Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: February 24, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY Explorer

Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device Identification:

Siemens Infinity Explorer, 510(k) K013515

Description of Modification:

The INFINITY EXPLORER is a software-driven application that allows the user to extend the viewing capability of the Infinity modular monitors (SC 7000, 8000 9000XL) and integrate additional patient information on a single display. INFINITY EXPLORER is capable of displaying real-time patient data, providing control back to the bedside and integrating other applications with patient data on the PC. In the initial release of the Infinity EXPLORER, the software was run on Siemens' own dedicated Medside Data Station (MDS), a patient vicinity computer based on Low Power Intel Pentium-III embedded processor.

The subject of this submission is a modification implemented that enables the INFINITY EXPLORER to run on a commercially available patient vicinity computer. With the release of software version VF2.1 the INFINITY EXPLORER has been tested for use with the Medside Data Station II (MDS II).

Intended Use:

The INFINITY EXPLORER is a critical care workstation intended to display physiological parameters received from INFINITY Modular Monitors and to visually display alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: Section J

COMPANY CONFIDENTIAL

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Siemens Medical Solutions, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K030615
Trade Name: Infinity Explorer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: 74 MSX
Dated: February 24, 2003
Received: February 26, 2003

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030615

510(k) Number (if known):_____

Device Name: Siemens INFINITY EXPLORER

Indications for Use:

This device is capable of displaying physiological parameters received from INFINITY monitors (SC 7000, SC 8000, SC 9000XL) and visually displaying alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

The device is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended for use with the adult, pediatric and neonatal populations.

MRI Compatibility Statement:
The Siemens INFINITY EXPLORER is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030615